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Weber et al.

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(54) **ENDOPROSTHESIS DEVICES INCLUDING BIOSTABLE AND BIOABSORABLE REGIONS**

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A61F 2/856 (2013.01)
A61F 2/82 (2013.01)

(52) **U.S. Cl.**

CPC ***A61F 2/915*** (2013.01); ***A61F 2/856*** (2013.01); *A61F 2002/061* (2013.01); *A61F 2002/825* (2013.01); *A61F 2002/91541* (2013.01); *A61F 2002/91575* (2013.01); *A61F 2250/0018* (2013.01); *A61F 2250/0029* (2013.01); *A61F 2250/0031* (2013.01); *A61F 2250/0036* (2013.01); *A61F 2250/0039* (2013.01)

(58) **Field of Classification Search**

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USPC 623/1.15–1.31
See application file for complete search history.

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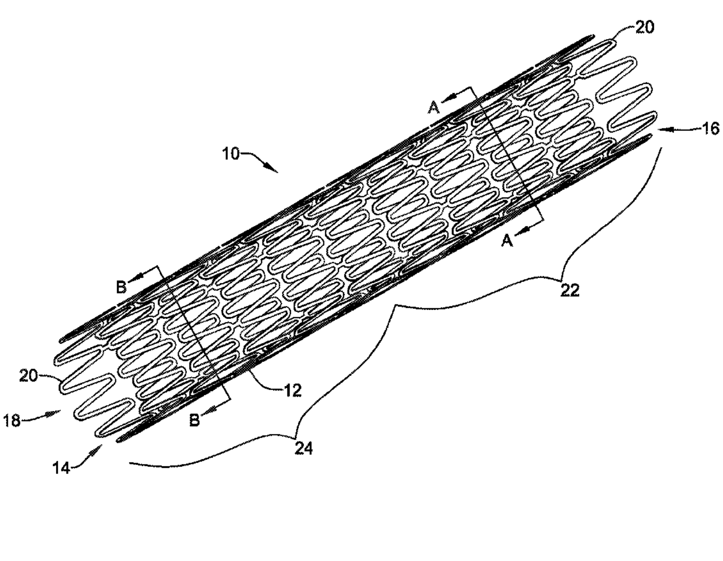
(57) **ABSTRACT**

Some embodiments are directed to medical devices, and methods for making and using the medical devices. An exemplary endoprosthesis includes an expandable tubular framework having a proximal end, a distal end, and a lumen extending therethrough. The tubular framework includes a number of interconnected biostable struts. The tubular framework has a proximal region extending distally from the proximal end to an intermediate location, and a distal region extending proximally from the distal end to the intermediate location. The distal region of the tubular framework is more flexible than the proximal region.

17 Claims, 15 Drawing Sheets



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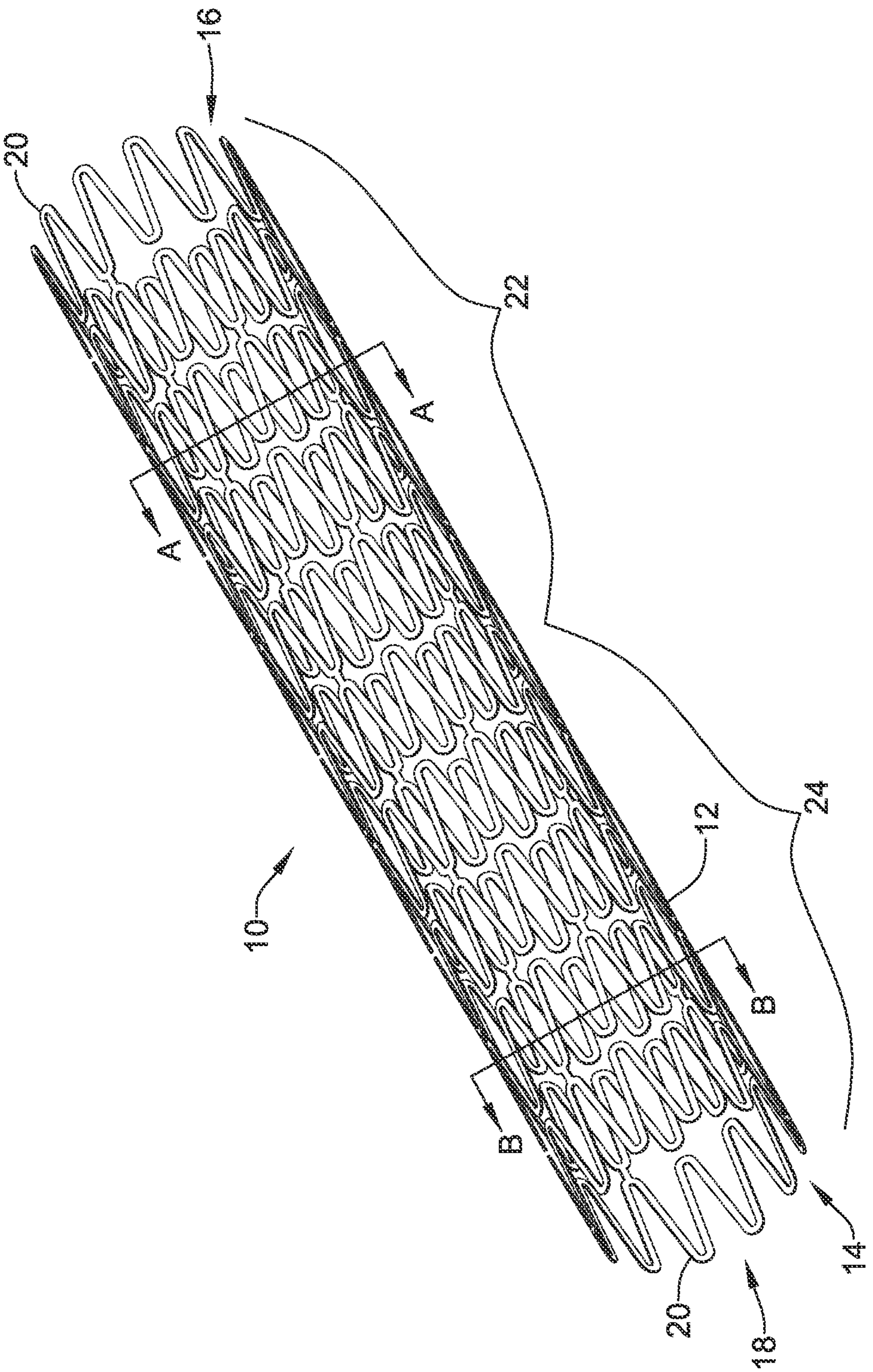


Figure 1

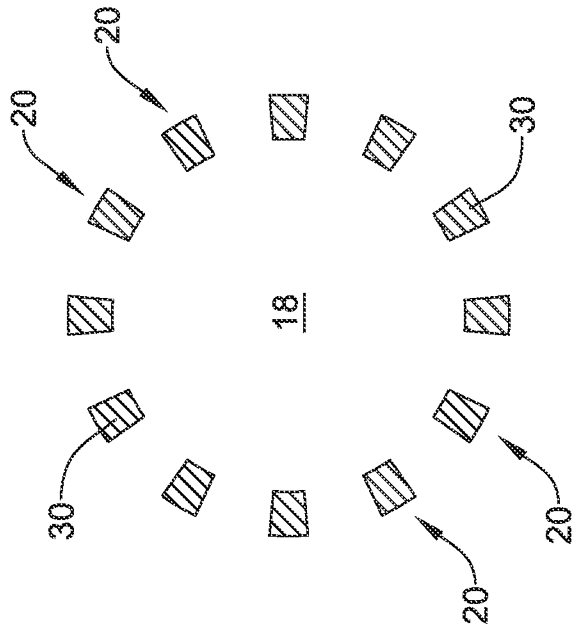


Figure 2B

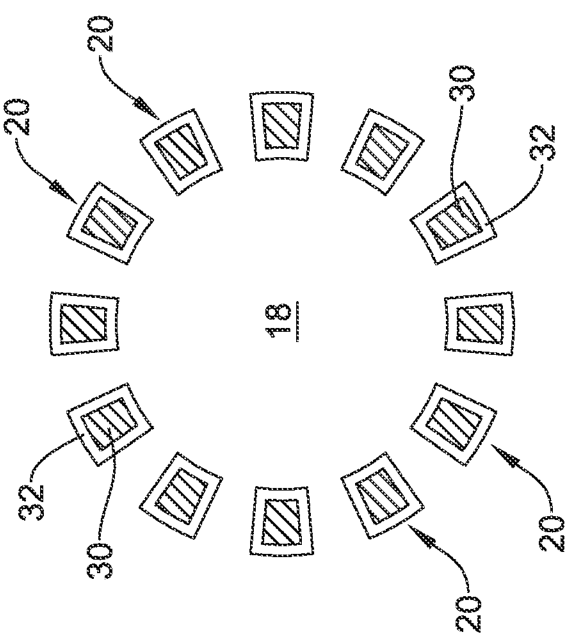


Figure 2A

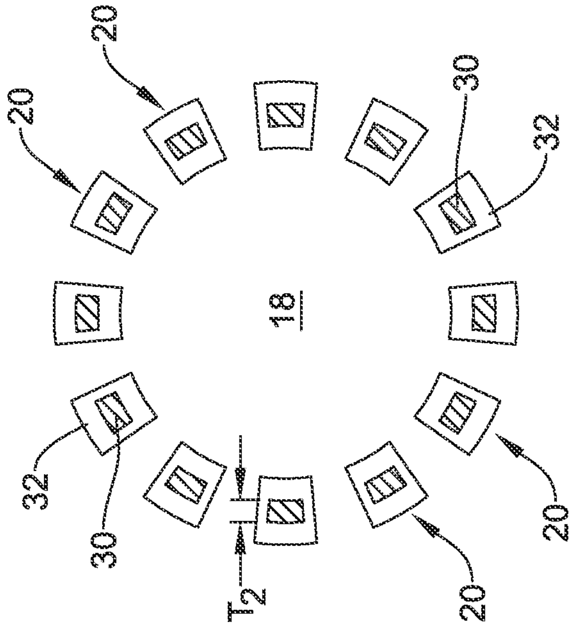


Figure 3B

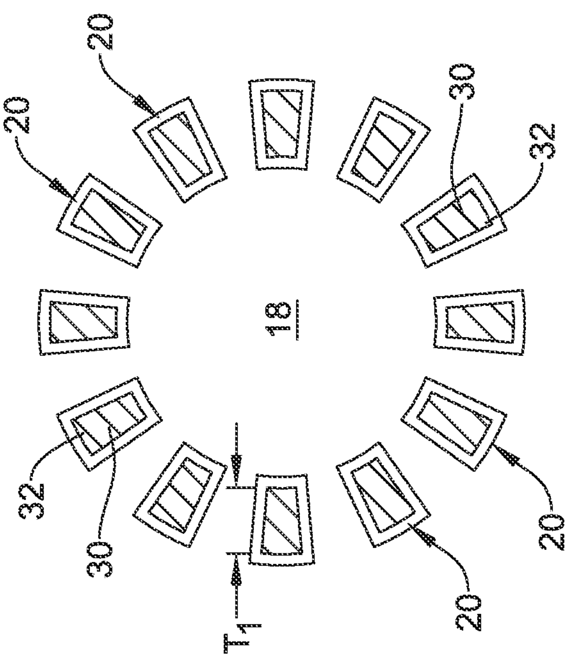


Figure 3A

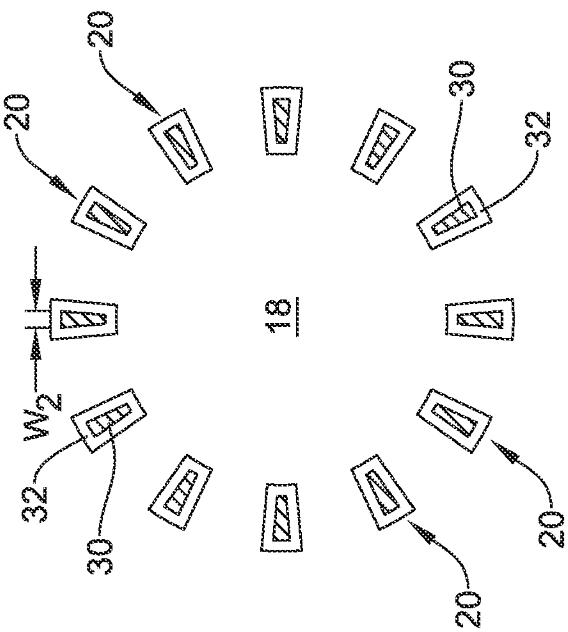


Figure 4B

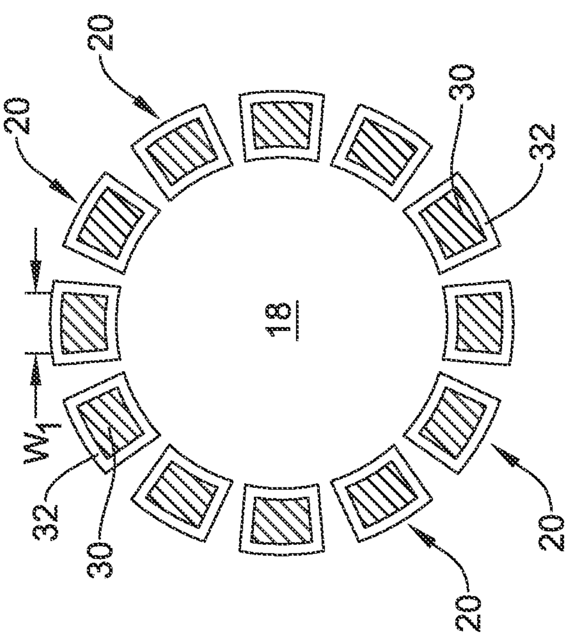


Figure 4A

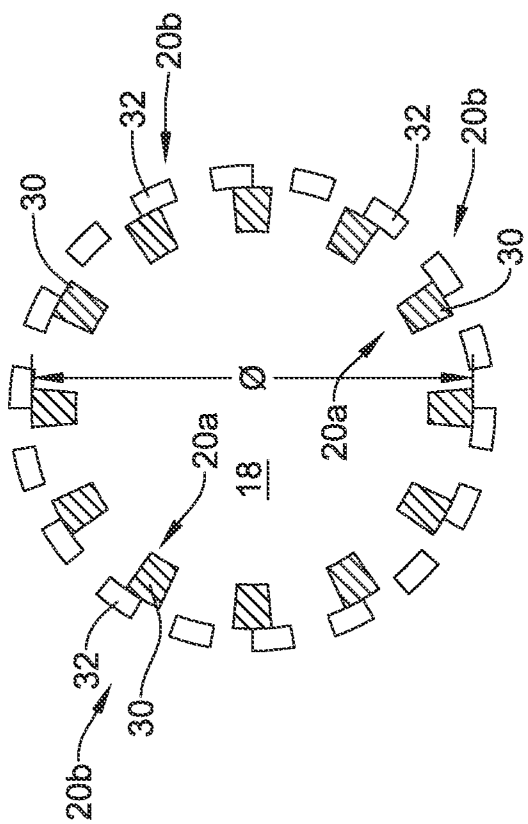


Figure 5A

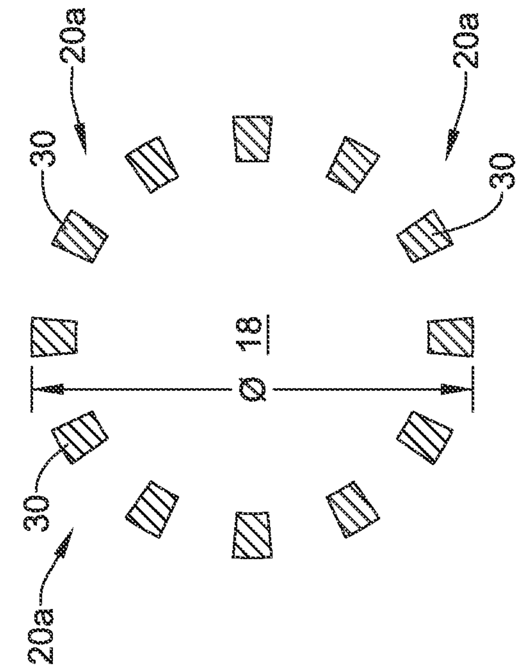


Figure 5B

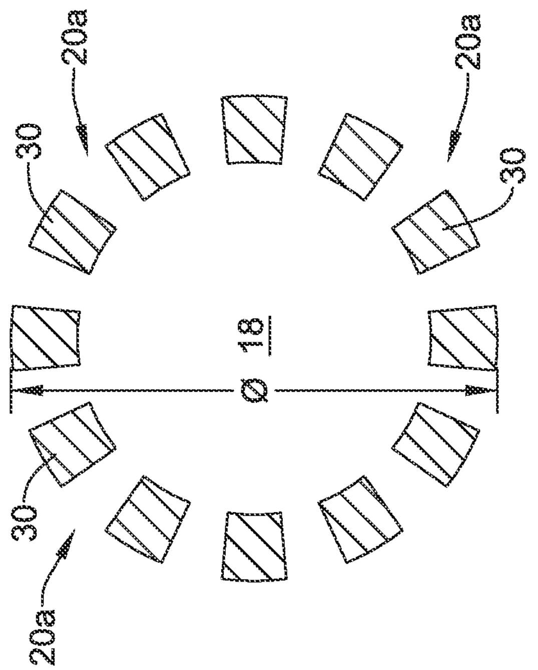


Figure 6B

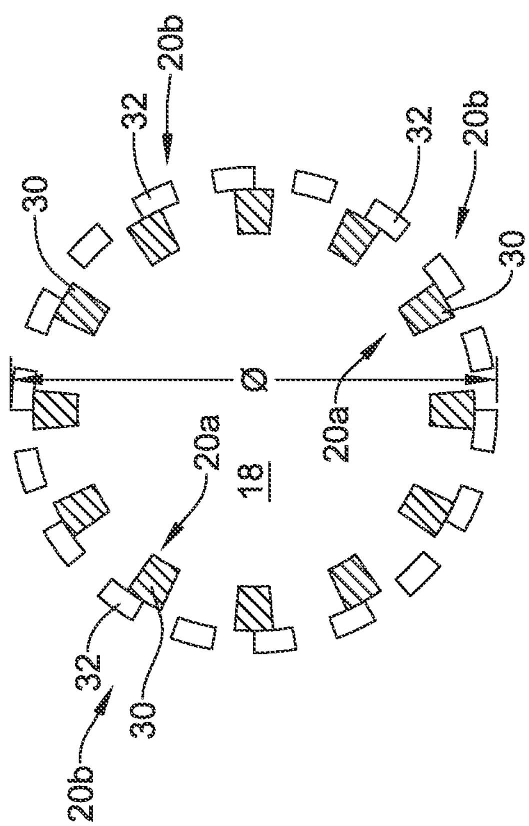


Figure 6A

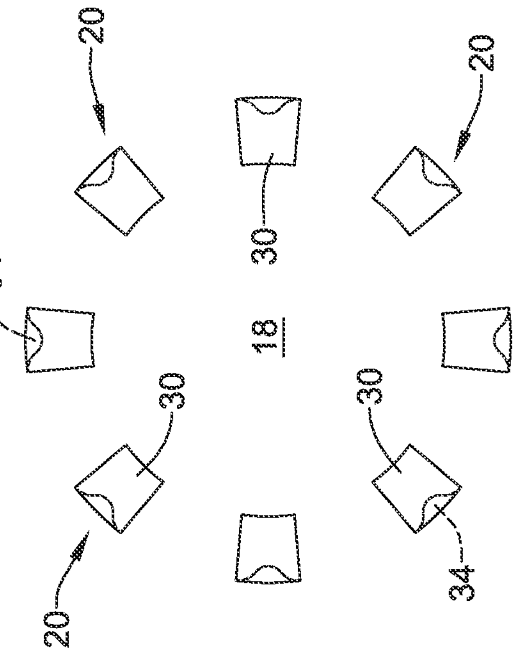


Figure 7B

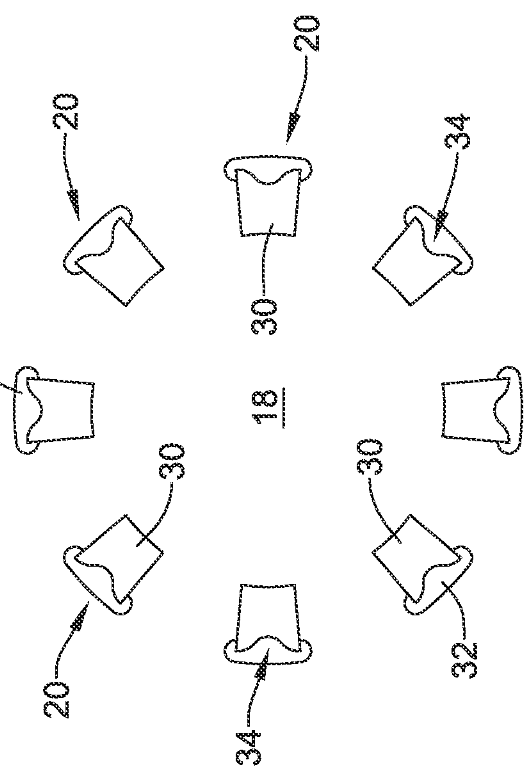


Figure 7A

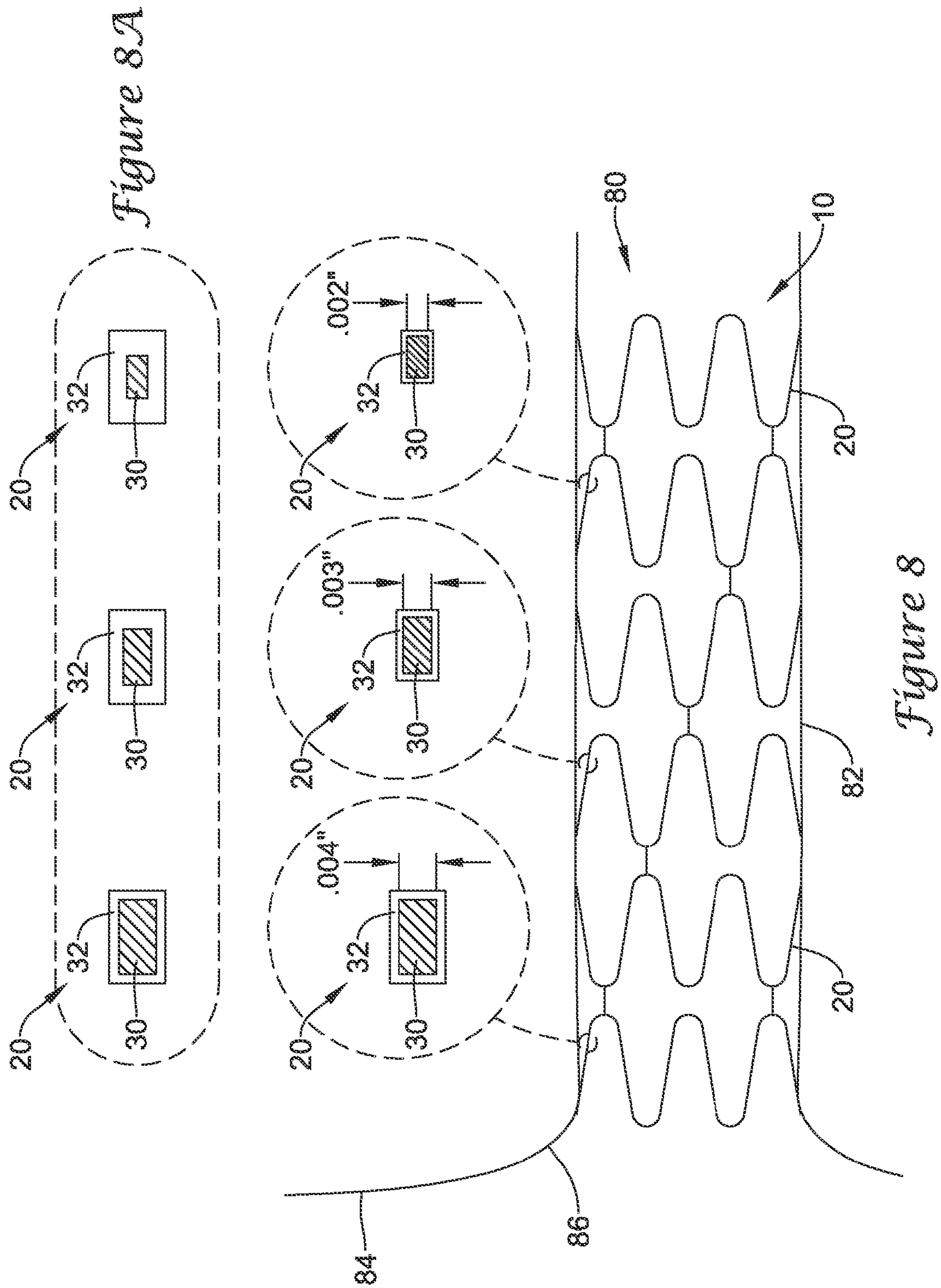
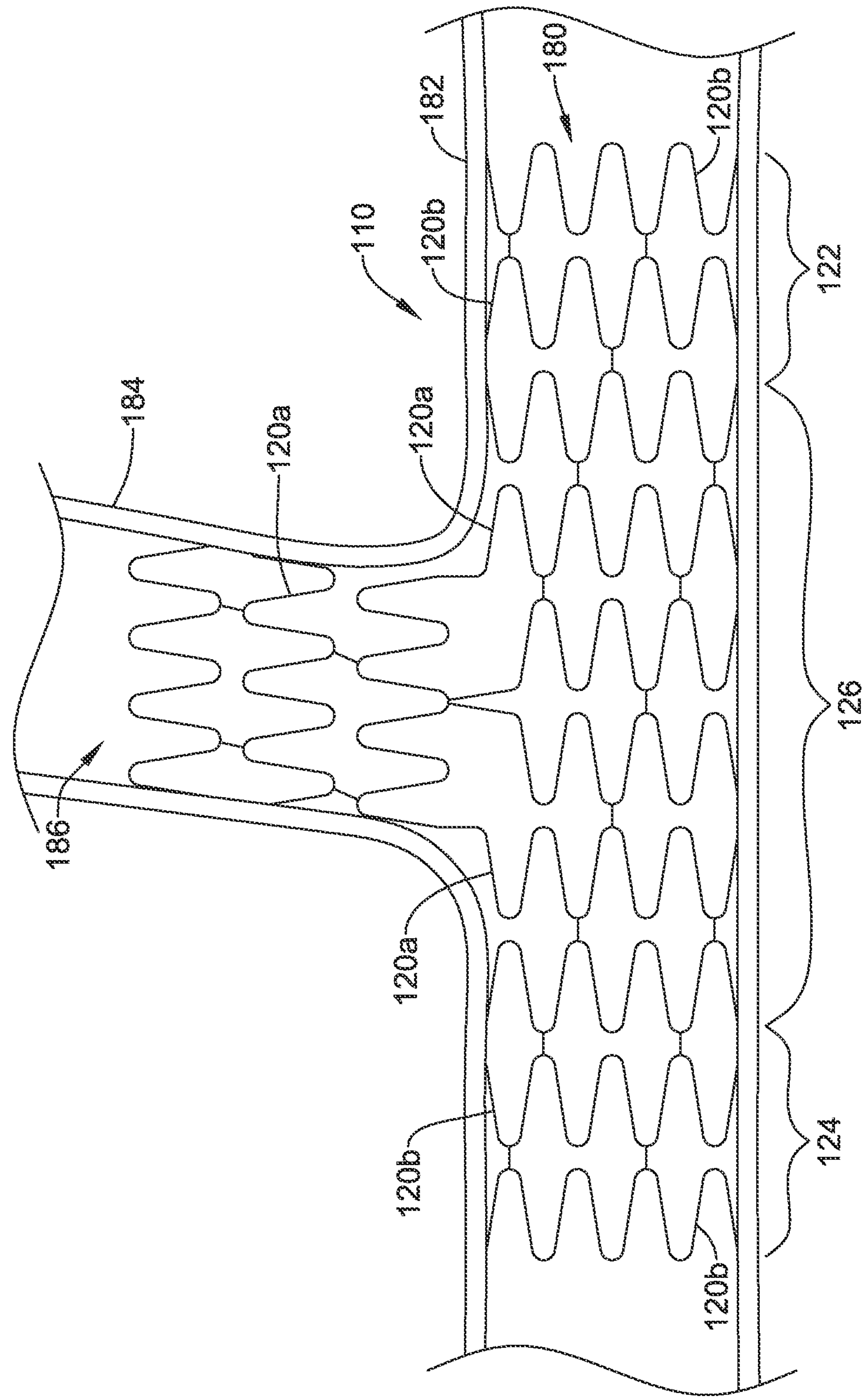


Figure 8A

Figure 8


180
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126
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120b
120b

Figure 9

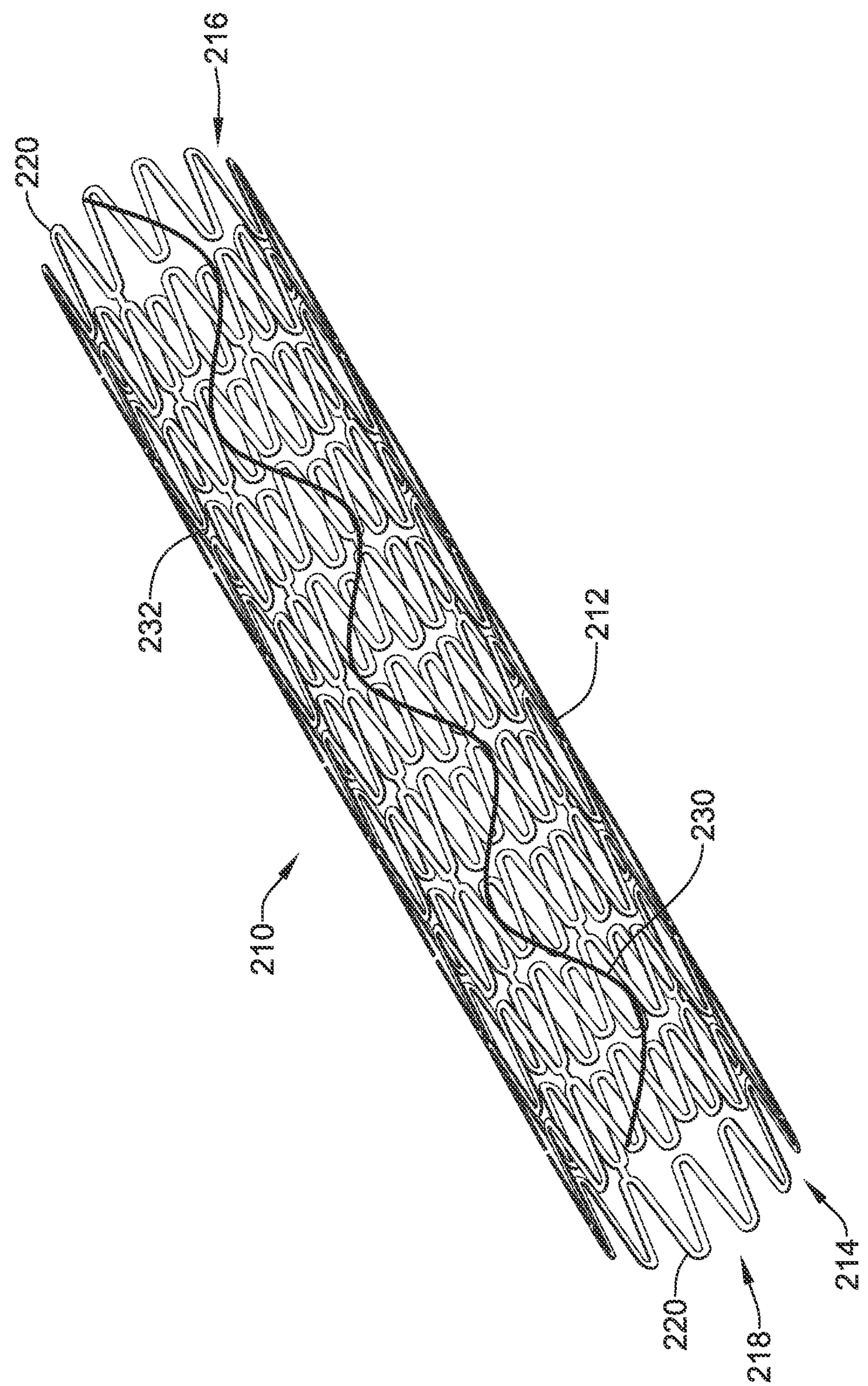

Figure 10

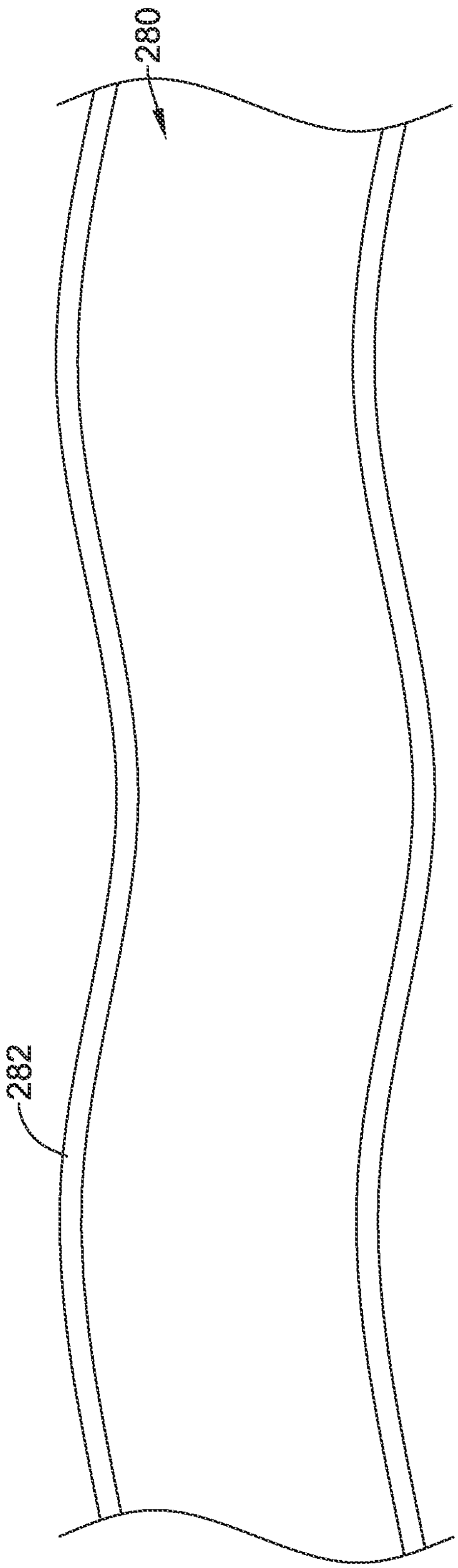

Figure 11A

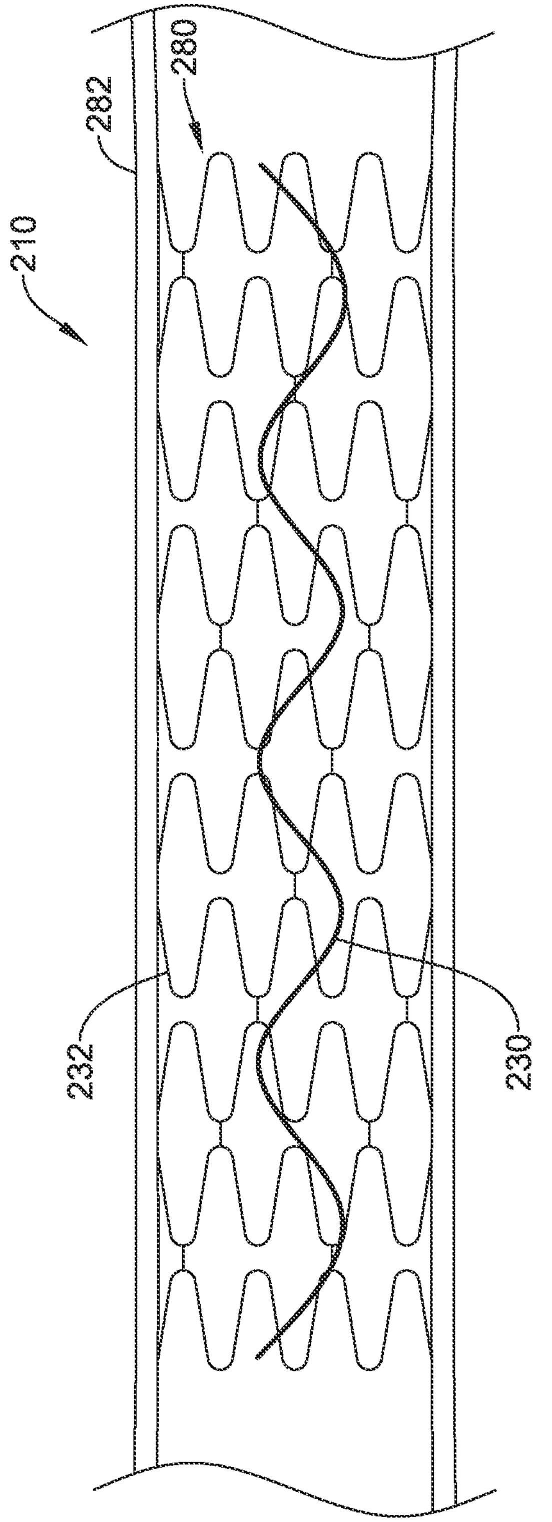

Figure 11B

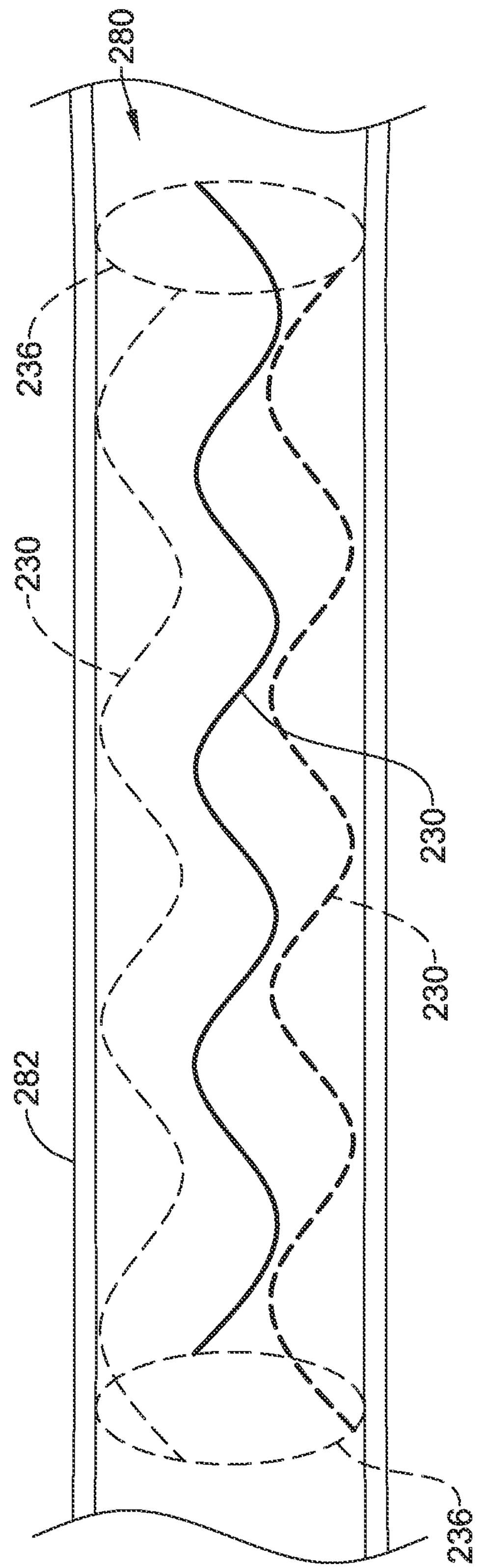

Figure 11C

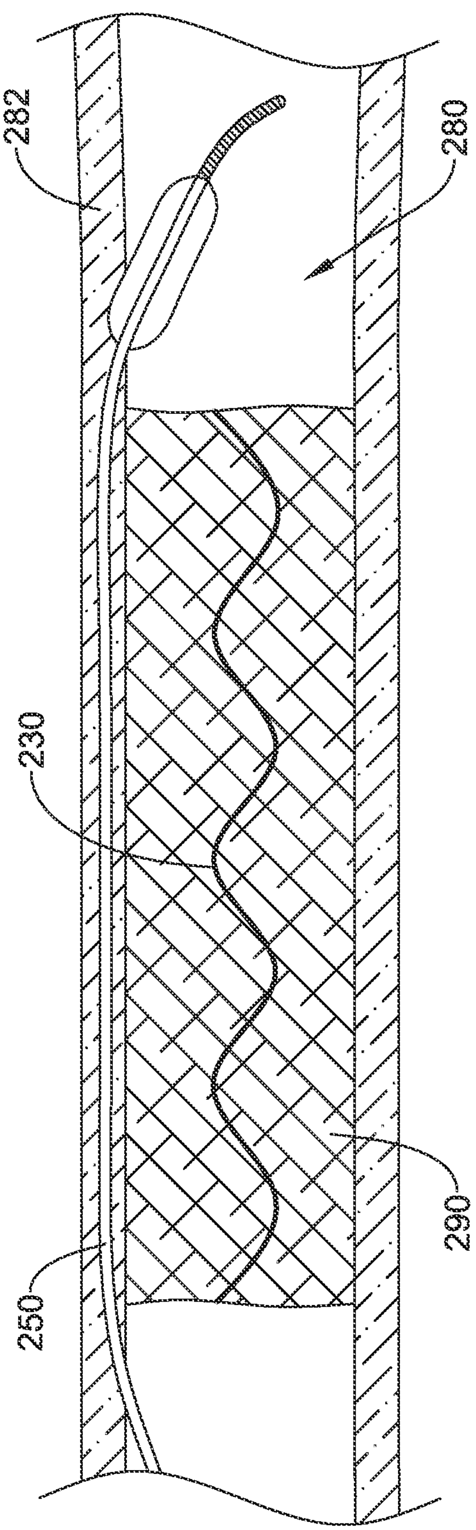

Figure 12A

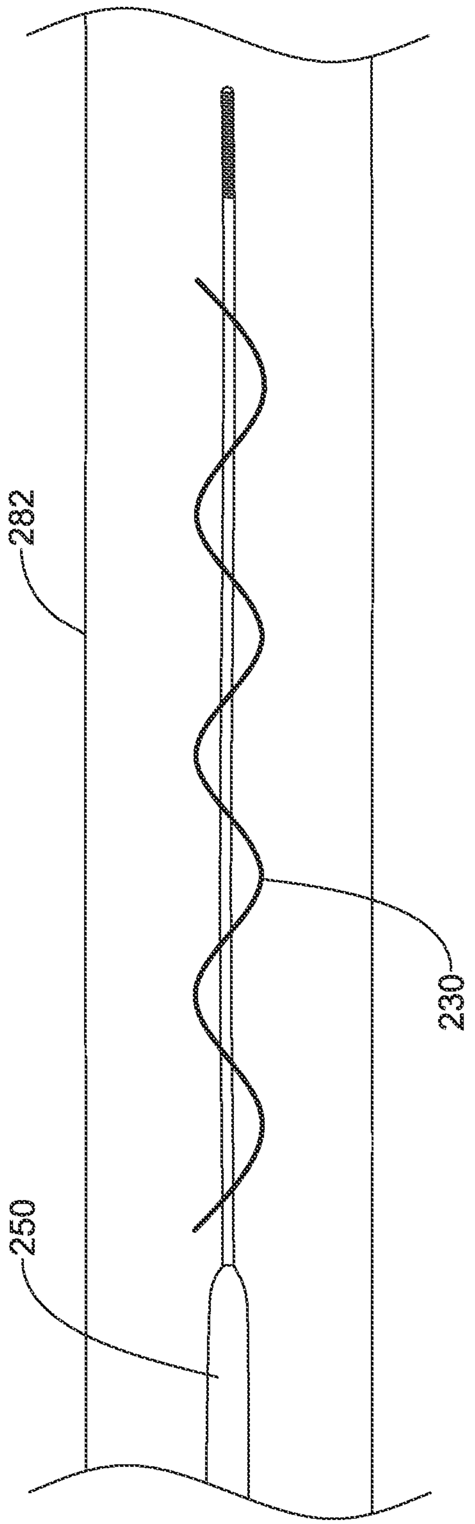

Figure 12B

ENDOPROSTHESIS DEVICES INCLUDING BIOSTABLE AND BIOABSORABLE REGIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Ser. No. 61/875,370, filed Sep. 9, 2013, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

Some embodiments relate to medical devices, such as endoprostheses, and methods for manufacturing and using the medical devices. For example, endoprostheses including bioabsorbable portions and biostable portions are disclosed.

BACKGROUND

The body includes various passageways including blood vessels, such as arteries, urinary, biliary, tracheobronchial, esophageal or renal tracts, and other body lumens. These passageways sometimes become occluded or weakened, or otherwise structural support may be desired. For example, they can be occluded by a tumor, restricted by plaque, or weakened by an aneurysm. When this occurs, the passageway can be reopened or reinforced, or even replaced, with a medical endoprosthesis. The endoprosthesis may be implanted in a passageway or lumen in the body. Many endoprostheses are tubular members, examples of which include stents, stent grafts, covered stents, aortic valves, etc.

Some endoprostheses are made from fully bioabsorbable materials which will gradually dissolve or be absorbed by the body over a period of time after implantation. Other endoprostheses are made from biostable materials, such as biostable metallic materials and/or polymeric materials which will remain in the body lumen indefinitely after implantation.

The endoprosthesis should exhibit sufficient strength to retain the endoprosthesis at the desired location within the anatomy. For instance, regarding stents configured to be placed proximate an aortic ostium, it may be desirable to configure the stent to have a proximal region positioned proximate the aortic ostium that is stronger than a distal region of the stent extending into the coronary artery away from the aortic ostium due, at least in part, to the larger forces involved and the larger diameter of the vessel on the ostium side. However, it may be desirable to maintain flexibility along other portions of the stent. In other applications, such as in the tortuous vasculature, it may be desirable to utilize a stent that provides sufficient initial stability to the vessel, but over time restores vasomotion in the stented vessel.

Accordingly, it may be beneficial to provide alternative endoprostheses as well as methods for manufacturing and using the alternative endoprostheses that provide sufficient structural support while maintaining a desired flexibility. Some embodiments are therefore directed to several alternative designs of endoprosthesis structures and assemblies, as well as methods of making and using the alternative endoprosthesis structures and assemblies.

SUMMARY

One illustrative embodiment includes an endoprosthesis having an expandable tubular framework. The tubular framework has a proximal end, a distal end, and a lumen extending therethrough. The tubular framework includes a number of interconnected biostable struts. A proximal region of the tubular framework extends distally from the proximal end to an intermediate location, and a distal region of the tubular framework extends proximally from the distal end to the intermediate location. The distal region of the expandable tubular framework is more flexible than the proximal region.

Another embodiment of an endoprosthesis includes an expandable tubular framework. The tubular framework has a first end, a second end, and a lumen extending therethrough. The tubular framework includes a number of interconnected bioabsorbable struts. At least one biostable wire extends generally longitudinally along the tubular framework. The biostable wire is configured to provide longitudinal support to a vessel wall after the tubular framework is absorbed.

Yet another illustrative embodiment includes a method of implanting an endoprosthesis that has an expandable tubular framework in a coronary artery proximate to an aortic ostium. The tubular framework has a proximal end, a distal end, and a lumen extending therethrough. The tubular framework includes a number of interconnected biostable struts, and a bioabsorbable material disposed on a portion of the interconnected biostable struts. The endoprosthesis is positioned in the coronary artery with the proximal end proximate to the aortic ostium. The method also includes expanding the tubular framework to exert a radially outward force against the coronary artery. A proximal region of the endoprosthesis proximate to the proximal end has an initial stiffness if expanded that is greater than an initial stiffness of a distal region of the endoprosthesis. The proximal region is configured to have a reduced stiffness that is less than the initial stiffness over a period of time as the bioabsorbable material is absorbed. The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments, but are also intended as exemplary and not limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. **1** is a perspective view of an exemplary endoprosthesis;

FIGS. **2**A and **2**B are exemplary cross-sectional views taken along lines A-A and B-B of FIG. **1**, respectively, in which a proximal portion of the endoprosthesis includes a bioabsorbable material disposed on the biostable struts;

FIGS. **3**A and **3**B are alternative cross-sectional views taken along lines A-A and B-B of FIG. **1**, respectively, in which the thickness of the proximal struts is greater than the thickness of the distal struts, and a bioabsorbable material is disposed at or on the biostable struts;

FIGS. **4**A and **4**B are alternative cross-sectional views taken along lines A-A and B-B of FIG. **1**, respectively, in which the width of the proximal struts is greater than the width of the distal struts, and a bioabsorbable material is disposed at or on the biostable struts;

FIGS. **5**A and **5**B are alternative cross-sectional views taken along lines A-A and B-B of FIG. **1**, respectively, in which the proximal region of the endoprosthesis includes a bioabsorbable expandable framework disposed at or on a biostable expandable framework;

FIGS. **6**A and **6**B are alternative cross-sectional views taken along lines A-A and B-B of FIG. **1**, respectively, in which the proximal region of the endoprosthesis includes a bioabsorbable expandable framework disposed at or on a biostable expandable framework;

FIGS. **7**A and **7**B are alternative cross-sectional views taken along lines A-A and B-B of FIG. **1**, respectively, in which the proximal region of the endoprosthesis includes a bioabsorbable material disposed in a channel of the biostable struts;

FIG. **8** is a cross-sectional view illustrating placement of an exemplary endoprosthesis at the aorta ostium, the illustrative endoprosthesis including a biostable expandable framework having a varying thickness along its length and a bioabsorbable material disposed on the biostable struts;

FIG. **8**A are alternative cross-sectional views of the endoprosthesis of FIG. **8**;

FIG. **9** is a cross-sectional view illustrating placement of an exemplary endoprosthesis in a bifurcated vessel;

FIG. **10** is a perspective view of an alternative endoprosthesis including a biostable wire;

FIGS. **11**A-**11**C illustrate aspects of using the endoprosthesis of FIG. **10** in a vessel; and

FIGS. **12**A-**12**B illustrate advantages of the biostable wire of the endoprosthesis of FIG. **10**.

DETAILED DESCRIPTION

Definitions of certain terms are provided below and shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same or substantially the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

The recitation of numerical ranges by endpoints includes all numbers within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms "a," "an," and "the" include or otherwise refer to singular as well as plural referents, unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed to include "and/or," unless the content clearly dictates otherwise.

The following detailed description should be read with reference to the drawings, in which similar elements in different drawings are identified with the same reference numbers. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure.

FIG. **1** illustrates an exemplary endoprosthesis **10**. The endoprosthesis **10** may be configured to be positioned in a body lumen for a variety of medical applications. For example, the endoprosthesis **10** may be used to treat a stenosis in a blood vessel, used to maintain a fluid opening or pathway in the vascular, urinary, biliary, tracheobronchial, esophageal or renal tracts, or position a device such as an artificial valve or filter within a body lumen, in some instances. In some instances, the endoprosthesis **10** may be a prosthetic graft, a stent-graft, or a stent (e.g., a vascular stent, tracheal stent, bronchial stent, esophageal stent, etc.), an aortic valve, filter, etc. Although illustrated as a stent, the endoprosthesis **10** may be any of a number of devices that may be introduced endoscopically, subcutaneously, percutaneously or surgically to be positioned within an organ, tissue, or lumen, such as a heart, artery, vein, urethra, esophagus, trachea, bronchus, bile duct, or the like.

The endoprosthesis **10** may include a proximal end **16**, a distal end **14**, and an expandable tubular framework **12** disposed about a longitudinal axis of the endoprosthesis **10** that defines a lumen **18** extending therethrough. The term 'expandable tubular framework **12**' may be referred to as 'expandable framework **12**' hereafter. The expandable framework **12** may include a number of interconnected struts **20** to form a mesh-like structure of the expandable framework **12**. The struts **20** may be configured to transition from a compressed state to an expanded state.

The expandable framework **12** may include a proximal region **22** and a distal region **24**, which are separated by an intermediate location. The proximal region **22** includes the proximal end **16** and extends distally therefrom to the intermediate location. The distal region **24** extends distally from the intermediate location to the distal end **14**. In other words, the distal region **24** extends proximally from the distal end **14** to the intermediate location. The intermediate location can be or otherwise define a midpoint in the direction of elongation of the expandable framework **12**, such that the proximal and distal regions **22**, **24** have the same lengths. Alternatively, the intermediate location can be disposed at a location other than the midpoint, such that the proximal and distal regions **22**, **24** have different lengths.

The endoprosthesis **10** may be configured to be implanted in the vasculature of a patient, such as an aortic ostium, tortuous vessels, etc. In other embodiments, the endoprosthesis **10** may be configured to be implanted in the urinary, biliary, tracheobronchial, esophageal or renal tracts, for example. Since the endoprosthesis **10**, or a portion thereof, may be intended to be implanted permanently in the body lumen, the endoprosthesis **10** may be made, at least in part, from a biostable material. Examples of the biostable metal materials may include, but are not limited to, stainless steel, tantalum, tungsten, niobium, platinum, nickel-chromium alloys, cobalt-chromium alloys such as Elgiloy® and Phynox®, nitinol (e.g., 55% nickel, 45% titanium), and other alloys based on titanium, including nickel titanium alloys, or other suitable metals, or combinations or alloys thereof. Some suitable biostable polymeric materials include, but are not necessarily limited to, polyamide, polyether block amide, polyethylene, polyethylene terephthalate, polypropylene, polyvinylchloride, polyurethane, polytetrafluoroethylene, polysulfone, and copolymers, blends, mixtures or combinations thereof.

Further, the struts **20** of the proximal region **22** may be coated with a bioabsorbable material or otherwise include a bioabsorbable material, thereby increasing the initial strength of the proximal region **22**, such as by increasing the width, thickness, configuration, or other property of the proximal region **22**. This coating may increase thickness of the struts **20** of the proximal region **22**, thereby providing more stiffness to the proximal region **22**. Such structure may be used, for example, in an aortic ostium, where larger forces are required and diameter of the vessel on the ostium side of the aortic ostium is larger.

Examples of suitable bioabsorbable materials may include polymers, such as poly-L-lactide (PLLA), polyglycolide (PGA), polylactide (PLA), poly-D-lactide (PDLA), polycaprolactone, polydioxanone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), and combinations thereof. The bioabsorbable material may be disposed at or on the proximal region **22** in different configurations. Some different embodiments of such configurations will be discussed in detail in conjunction with subsequent figures.

In some embodiments, the struts **20** of the endoprosthesis **10** may be arranged in suitable pattern, such as a serpentine configuration, a mesh, a fenestrated pattern, or other arrangement. For example, a number of the struts **20** can form a number of alternating peaks and troughs. The struts **20** may have an outer surface and an inner surface. In some embodiments, the outer surface is the abluminal surface of the endoprosthesis **10**, and the inner surface is the luminal surface of the endoprosthesis **10**. A thickness of the struts **20** may be measured between the outer surface and the inner surface in a radial direction from the central longitudinal axis of the endoprosthesis **10**. A width of the struts **20** may be measured perpendicular to the thickness between side surfaces of the struts **20**. Each of the struts **20** of the expandable framework **12** has a width W, and a thickness T.

FIGS. **2**A and **2**B are exemplary cross-sectional views taken along the lines A-A and B-B of FIG. **1**, respectively. As shown in FIG. **2**A, the bioabsorbable material **32** may be disposed around the struts **20** of the proximal region **22**. Hence, a layer of the bioabsorbable material **32** may surround or encapsulate the biostable material **30** of the struts **20**. As shown in FIG. **2**B, the distal region **24** may be devoid of the bioabsorbable material **32**, thus exposing the biostable material **30**. The bioabsorbable material **32** may be absorbed by the body of a patient through the blood stream, other fluids and/or other natural compositions, over a period of time after implanting the endoprosthesis **10** within the body lumen.

In some embodiments, for example as shown in FIGS. **3**A and **3**B, the thickness (T_1) of the biostable material **30** of the struts **20** located at the proximal region **22** may be greater than the thickness (T_2) of the biostable material **30** of the struts **20** located at the distal region **24**. As shown in FIGS. **3**A and **3**B, the thickness T_1 of the biostable material **30** of the struts **20** in the proximal region **22** may be greater than the thickness T_2 of the biostable material **30** of the struts **20** of the distal region **24**. Greater thickness of the struts **20** of the proximal region **22** may be provided to increase strength of the proximal region **22** as compared to the distal region **24**, as required in body lumens such as the aorta ostium. A layer of the bioabsorbable material **32** may be disposed on and/or around the biostable material **30** of the struts **20** of the proximal region **22**, thereby increasing the thickness and hence strength of the proximal region **22**. As shown in FIG. **3**B, the biostable material **30** of the struts **20** of the distal region **24** may also be coated or covered by the bioabsorbable material **32**. In some instances the thickness of the bioabsorbable material **32** may be constant throughout the proximal region **22** and the distal region **24**. In other instances, the thickness of the bioabsorbable material **32** throughout the proximal region **22** may be different from the thickness of the bioabsorbable material **32** throughout the distal region **24**. For example, the thickness of the bioabsorbable material **32** may be greater in the distal region **24** than the proximal region **22**, such that the thickness of the struts **20** may be constant throughout the length of the endoprosthesis **10**. In some instances, the distal region **24** may be coated with the bioabsorbable material **32** such that there is a continuous variation in thickness from the proximal region **22** to the distal region **24**.

In some embodiments, the width of the struts **20** of the proximal region **22** may be different than (e.g., greater than or less than) the width of the struts **20** in the distal region **24**. FIGS. **4**A and **4**B are alternative cross-sectional views taken along the lines A-A and B-B of FIG. **1**, respectively. In this embodiment, the width W_1 of the biostable material **30** of the struts **20** of the proximal region **22** may be greater than the width W_2 of the biostable material **30** of the struts **20** in the distal region **24**, thereby increasing strength of the struts **20** of the proximal region **22**. The bioabsorbable material **32** may be disposed on and/or around the biostable material **30** of the struts **20** in the proximal region **22** and/or the distal region **24**. In some instances the thickness of the bioabsorbable material **32** may be constant throughout the proximal region **22** and the distal region **24**. In other instances, the thickness of the bioabsorbable material **32** throughout the proximal region **22** may be different from the thickness of the bioabsorbable material **32** throughout the distal region **24**. For example, the thickness of the bioabsorbable material **32** may be greater in the distal region **24** than the proximal region **22**, such that the width of the struts **20** may be constant throughout the length of the endoprosthesis **10**. In some instances, the interconnected struts **20** may have a continuously changing width from the proximal region **22** to the distal region **24**.

In some embodiments, for example as shown in FIG. **5**A, the bioabsorbable material **32** may be provided by a bioabsorbable expandable framework including a number of interconnected bioabsorbable struts **20*b*** disposed on a biostable expandable framework including a number of interconnected biostable struts **20*a*** in the proximal region **22**. In such an embodiment, a circumferential arrangement of biostable struts **20*a*** may be beneath a circumferential arrangement of bioabsorbable struts **20*b***. In other words, a bioabsorbable expandable framework of the bioabsorable material **32** may surround a biostable expandable framework of the biostable material **30** throughout the proximal region **22**. The biostable struts **20*a*** may be made from the biostable material **30** and the bioabsorbable struts **20*b*** may be made from the bioabsorbable material **32**. As shown in FIG. **5**B, the distal region **24** of the expandable framework **12** may be devoid of the bioabsorbable struts **20*b***, and may include a circumferential arrangement of the biostable struts **20*a*** formed of the biostable material **30**. The expandable tubular framework **12** may have a first outer diameter in the proximal region **22** and a second diameter in the distal region **24**.

As shown in FIGS. **5**A and **5**B, the outer diameter of the biostable struts **20*a*** may be constant throughout the proximal region **22** and the distal region **24**. Thus, the expandable tubular framework **12** may have a non-uniform outer diameter, with a larger outer diameter throughout the proximal region **22** due to the inclusion of the bioabsorbable struts **20*b*** surrounding the biostable struts **20*a***, and a smaller outer diameter throughout the distal region **24** due to the absence of the bioabsorbable struts **20*b*** in the distal region **24**. Therefore, the expandable framework **12** may initially have a non-uniform outer diameter, however once the bioabsorbable struts **20*b*** are absorbed, the expandable framework **12** may have a uniform outer diameter.

In alternative embodiments, such as shown in FIGS. **6**A and **6**B, the outer diameter of the proximal region **22** may be equal to the outer diameter of the distal region **24**, so that the expandable framework **12** may initially have a constant outer diameter throughout its length i.e. from the proximal end **16** to the distal end **14**. In such an embodiment, the outer diameter of the biostable struts **20*a*** may be smaller throughout the proximal region **22** than the outer diameter of the biostable struts **20*a*** throughout the distal region **24**. For example, the biostable framework may have a necked down region between the proximal region **22** and the distal region **24** to provide the change in outer diameter. The bioabsorbable framework defined by the bioabsorbable struts **20*b*** may surround the reduced diameter proximal region **22** of the biostable struts **20***a*. In some instances, the outer diameter of the bioabsorbable framework in the proximal region **22** may be approximately equal to the outer diameter of the biostable framework in the distal region **24**. Thus, the expandable tubular framework **12** may have a uniform outer diameter throughout its length.

FIGS. **7**A and **7**B are alternative cross-sectional views taken along the lines A-A and B-B of FIG. **1**. respectively. The expandable framework **12** may be made from the biostable material **30**. In an embodiment, a groove or channel **34** may be disposed in a surface, such as an outer surface, of the biostable struts **30** in the proximal region **22** of the expandable framework **12**. The bioabsorbable material **32** may be disposed in the grooves or channels **34** of the biostable struts **30** in the proximal region **22** to increase the initial strength of the proximal region **22**. However, the distal region **24**, which may or may not include the grooves or channels **34** in the biostable struts **30**, may be devoid of the bioabsorbable material **32**, or may include a lesser amount of the bioabsorbable material **32**. Over a period of time as the bioabsorbable material **32** is absorbed by the body, the strength of the proximal region **22** may be reduced from the initial strength of the proximal region **22**.

FIG. **8** is a cross-sectional view illustrating placement of an exemplary endoprosthesis at an aorta ostium **86**. In the cardiovascular system, the aorta **84** branches into a coronary vessel **82** at a branch point referred to as the aorta ostium **86**. The vessel **82** includes a vessel lumen **80**, into which the endoprosthesis **10** may be implanted. One of the endoprostheses discussed above may be positioned in the vessel lumen **80** with the proximal region **22** of the endoprosthesis **10** proximate the aorta ostium **86** and the distal region **24** of the endoprosthesis extending into the vessel lumen **80** distal of the aorta ostium **86**. Thus, the proximal region **22**, which may have an initial strength greater than the initial strength of the distal region **24** may facilitate retention of the endoprosthesis **10** proximate the aorta ostium **86**. The strength of the proximal region **22** may decrease over a period of time as the bioabsorbable material is absorbed by the patient, thus the strength of the proximal region **22** may be less than the initial strength of the proximal region **22**.

FIG. **8** illustrates another embodiment of the endoprosthesis **10** in which the endoprosthesis **10** may include a number of interconnected struts **20** made from the biostable material **30** and a layer of the bioabsorbable material **32** may be disposed on the biostable struts **20**. In the embodiment shown in FIG. **8**, the thickness of the biostable material **30** of the struts **20** may vary along the length of the endoprosthesis **10**. For instance, the thickness of the biostable material **30** of the struts **20** may vary continuously along the length of the endoprosthesis **10**, endoprosthesis **10** may include one or more stepped transitions in the thickness of the biostable material **30** of the struts **20** at different locations along the length of the endoprosthesis **10**, or the thickness of the biostable material **30** may change in another fashion. In some instances, the thickness of the biostable material **30** of the struts **20** in the distal region of the endoprosthesis **10** may be in a range of about 0.001 inches to about 0.002 inches, and the thickness of the biostable material **30** of the struts **20** in the proximal region of the endoprosthesis **10** may be in a range of about 0.003 inches to about 0.004 inches. In some instances, the thickness of the struts **20** in a middle region, intermediate the distal region and the proximal region of the endoprosthesis **10**, may be in a range of about 0.002 inches to about 0.003 inches, for example. Accordingly, the thickness of the struts **20** in the proximal region of the endoprosthesis **10** may be greater as compared to the thickness of the struts **20** in the middle and distal regions of the endoprosthesis **10**, thereby providing more strength to the struts **20** located in the proximal region of the endoprosthesis **10**. Also, the biostable material **30** may act as a scaffold to avoid or prevent the bioabsorbable material **32** from disengaging and drifting towards the main aortic vessels.

In some instances, the ratio of the biostable material **30** to the bioabsorbable material **32** may be 1:1. In other instances, the ratio of the biostable material **30** to the bioabsorbable material **32** may be 1:2, 1:3, 2:3, or 1:4 for example. In some embodiments, the ratio of the biostable material **30** to the bioabsorbable material **32** may increase or decrease along the length of the endoprosthesis **10**. For example, in some instances, the ratio of the biostable material **30** to the bioabsorbable material **32** may change (e.g., increase or decrease) continuously along the length of the endoprosthesis **10** or may include one or more stepped transitions along the length of the endoprosthesis **10**.

In some instances, the thickness of the biostable material **30**, the bioabsorbable material **32**, and/or the total thickness of the struts **20**, may decrease from the proximal end to the distal end of the endoprosthesis **10**. In one embodiment, as shown with the alternative cross-sections shown in FIG. **8**A, corresponding to the cross-sections shown in FIG. **8**, the thickness of the bioabsorbable material **32** may increase from the proximal end to the distal end of the endoprosthesis **10**, as the thickness of the biostable material **30** decreases from the proximal end to the distal end of the endoprosthesis **10**, or the thickness of the bioabsorbable material **32** may increase from the proximal end to the distal end of the endoprosthesis **10**, as the thickness of the biostable material **30** remains constant. In other instances, the thickness of the bioabsorable material **32** may decrease from the proximal end to the distal end of the endoprosthesis **10**, as the biostable material **30** decreases or remains constant. The total thickness of the struts **20**, may increase, decrease, or remain constant from the proximal end to the distal end as the ratio of the biostable material **30** to the bioabsorbable material **32** changes (e.g., increases or decreases) along the length of the endoprosthesis **10**.

In some instances, the thickness of the biostable material **30**, the bioabsorbable material **32**, and/or the total thickness of the struts **20**, may decrease from the proximal end, the distal end, or the proximal and distal ends of the endoprosthesis **10** to a region between the proximal and distal ends of the endoprosthesis **10**. The thickness of the biostable material **30**, the bioabsorbable material **32**, and/or the total thickness of the struts **20** may likewise increase from the proximal end, the distal end, or the proximal and distal ends of the endoprosthesis **10** to a region between the proximal and distal ends of the endoprosthesis **10**. In some instances, the thickness of the biostable material **30**, the bioabsorbable material **32**, and/or the total thickness of the struts **20**, may increase or decrease along one or more regions along the longitudinal axis of endoprosthesis **10**.

FIG. **9** is a cross-sectional view illustrating placement of an exemplary endoprosthesis in a bifurcated vessel. The vessel **182** has a vessel lumen **180** and bifurcates into a branch vessel **184**. The branch vessel **184** includes a lumen **186**. An endoprosthesis, such as a stent **110**, may be implanted with a portion in each of the lumens **180**, **186**. The stent **110** may include a number of interconnected struts. The stent **110** can be implanted in the bifurcated vessel **182** and may include a bioabsorbable proximal segment **124** and a bioabsorbable distal segment **122**, with a biostable segment **126** located between the bioabsorbable proximal segment **124** and the bioabsorbable distal segment **122**. Each of the bioabsorbable segments **124**, **122** may include a number of interconnected bioabsorbable struts **120*b***. The biostable segment **126** may include a number of interconnected biostable struts **120*a***. At least a portion of the biostable struts **120*a*** of the intermediate segment **126** may extend into the vessel lumen **186** of the branch vessel **184** to provide support at the bifurcation. The biostable struts **120*a*** may be implanted in the branch vessel **184** so that the biostable struts **120*a*** extending into the branch vessel **184** may remain intact after the bioabsorbable struts **120*b*** have been absorbed by the body. In some embodiments, the stent **110** may be a branched stent such that a portion of the stent **110** extends to form a branched portion and a central axis of the branched portion is substantially perpendicular or oblique to a longitudinal axis of a main portion of the stent **110**.

Further, the bioabsorbable struts **120*b*** may be provided on either side of the biostable struts **120*a*** in the vessel **182** to provide initial structural support of the stent **110** in the vessel **182**. Over a period of time, the struts **120*b*** may get absorbed in the vessel **182**, leaving the biostable struts **120*a*** in place.

FIG. **10** is a top view of an alternative endoprosthesis including a biostable wire disposed along a portion of the length of the endoprosthesis. As shown in FIG. **10**, the endoprosthesis may include a stent **210**. The stent **210** may include an expandable tubular framework **212** having a proximal end **216**, a distal end **214**, and a number of interconnected struts **220** disposed about a longitudinal axis of the stent **210** that defines a lumen **218** therethrough. The struts **220** may form a mesh-like framework **212** as shown in FIG. **10**. The struts **220** may be formed from a bioabsorbable material to form bioabsorbable struts **232**. The bioabsorbable struts **232** may be capable of being absorbed in the body lumen after being implanted in the body lumen over a period of time. In some embodiments, a biostable wire **230**, or a plurality of biostable wires **230**, may be positioned along (e.g., laid over, interweaved with, laid under, etc.) the expandable framework **212** to provide structural support to the stent **210**. The biostable wire **230** may remain in the body lumen permanently even after the expandable framework **212** has been absorbed in the body lumen.

In some instances, the elongate biostable wire(s) **230** may extend generally longitudinal along the expandable framework **212**. In embodiments having a plurality of biostable wires **230**, the biostable wires **230** may be arranged uniformly or non-uniformly around the circumference of the expandable framework **212**. In some instances, the longitudinally extending wire(s) **230** may be substantially straight, while in other instances the longitudinally extending wire(s) **230** may follow an undulating, a curved, a helical, or other desired path.

Various aspects of implanting the stent **210** in a vessel **282** within the body of a patient are shown in FIGS. **11A-11C**. As shown in FIG. **11A**, the vessel **282**, which may follow a tortuous pathway in some instances, may include a vessel lumen **280**. The vessel **282** may be stenosed, weakened, or otherwise require intervention with the stent **210**. In some cases, the vessel **282** may be weakened by aneurysm. Accordingly, the stent **210** may be implanted within the vessel lumen **280** of the vessel **282**, as shown in FIG. **11B**. Different features have already been explained in FIG. **10**, such as the biostable wire **230** and the bioabsorbable struts **232**. In some embodiments, a number of the biostable wires **230** may be positioned along the bioabsorbable struts **232**. At some time after implantation, for example 2 years or more, the bioabsorbable struts **232** may be fully absorbed in the vessel **282**. However, the biostable wire(s) **230** may remain in the vessel lumen **280** even after absorption of the bioabsorbable struts **232** by the body of the patient, as shown in FIG. **11C**. The presence of the biostable wire(s) **230** may facilitate restoring vasomotion and strength of the vessel **282**, and may not interfere with radial compression/dilation of the vessel **282** after the bioabsorbable struts **232** have been fully absorbed. Additionally or alternatively, the biostable wire(s) **230** may serve as a permanent re-shaping scaffold, reducing or otherwise modifying the curvature of the vessel **282** even after absorption of the bioabsorbable struts **232**. For example, the biostable wire(s) **230** may provide a degree of straightening of the vessel **282**, thus making the vessel **282** less tortuous, through the permanent presence of the biostable wire(s) **230** after the bioabsorbable struts **232** have been absorbed and vasomotion has been restored.

In some embodiments, the stent **210** may include a plurality of biostable wires **230**, and one or more biostable rings, such as a biostable ring **236** disposed on either side of the biostable wires **230** proximate the ends of the stent **210**. The ring **236** may be provided to give a structural support to the biostable wires **230** and to remain the biostable wires **230** intact in the vessel lumen **280** after the bioabsorbable struts **232** have been fully absorbed. The diameter of the ring **236** may be such that the ring **236** fits into the vessel lumen **280**. In some instances, the ring **236** may be expanded in the vessel lumen **280** upon implantation of the stent **210**. In such an embodiment, over a period of time, along with the biostable wires **230**, the rings **236** may also remain in the vessel lumen **280** to retain the biostable wires **230**. The biostable wires **230** and the rings **236** may facilitate restoring vasomotion and strength of the vessel **282**, and may not interfere with radial compression/dilation of the vessel **282**.

FIGS. **12**A and **12**B are schematics that illustrate some advantages of the biostable wire **230** of the endoprosthesis of FIG. **10**. As shown in FIG. **12**A, the vessel **282** may include the vessel lumen **280**. At some time after implantation of the stent **210**, the vessel lumen **280** may become occluded by an occlusion **290** in the region of the stent **210**. As discussed above, the biostable wire **230** may remain in the vessel **282** after the bioabsorbable struts **232** have been absorbed by the body and thus may extend through a region including the occlusion **290**. In the case of restenosis, for example, there may be a situation when recanalization of the vessel **282** past the occlusion **290** and the biostable wire **230** may be desired. For example, in instances in which the occlusion **290** is a chronic total occlusion (CTO) or otherwise substantially occludes the lumen **280**, it may be impossible or impracticable to pass a recanalization device through the occlusion **290**. In such instances, recanalization of the vessel **282** via a subintimal pathway may be achieved with a medical device **250**, for example.

The biostable wire **230**, which may be visible using fluoroscopy, may facilitate guiding the medical device **250** through the subintimal pathway. For example, the biostable wire **230** may provide a visual indication of the extent of the occlusion **290** such that the physician may navigate the medical device **250** across the occlusion **290**.

FIG. **12**B is a top view of the biostable wire **230** in the vessel **282** and the medical device **250** introduced for subinitimal access across the occlusion **290**. As discussed above, the biostable wire **230** may be visible using fluoroscopy to facilitate guiding the medical device **250** through the subintimal pathway. Once the physician confirms that the distal end of the medical device **250** has passed distal of the occlusion **290**, reentry into the true lumen distal of the occlusion **290** may be achieved with the medical device **250**, or other medical device.

A method of implanting an endoprosthesis, such as an endoprosthesis described above, in a coronary artery proximate an aortic ostium may include a number of consecutive, non-consecutive, simultaneous, non-simultaneous, or alternative steps. The method may also include providing the endoprosthesis. The endoprosthesis may be implanted in the coronary artery with the proximal end proximate to the aorta ostium. The expandable framework may expand to exert a radially outward force against the coronary artery. The proximal region of the endoprosthesis proximate to the proximal end may have an initial stiffness when expanded. The initial stiffness of the proximal region may be greater than an initial stiffness of the distal region. The stiffness of the proximal region may be reduced to a greater extent as compared to that of the distal region over a period of time as the bioabsorbable material is absorbed.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps, without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one exemplary embodiment in other embodiments. The disclosure's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. An endoprosthesis comprising:

an expandable tubular framework having a proximal end, a distal end, and a lumen extending therethrough, the expandable tubular framework including a plurality of interconnected biostable struts;

the expandable tubular framework having a proximal region extending distally from the proximal end to an intermediate location and a distal region extending proximally from the distal end to the intermediate location;

wherein the distal region of the expandable tubular framework is more flexible than the proximal region;

wherein the proximal region of the expandable tubular framework includes a bioabsorbable material disposed on the interconnected biostable struts and the distal region of the expandable tubular framework is devoid of a bioabsorbable material;

wherein the proximal region of the expandable tubular framework includes a bioabsorbable tubular structure disposed around the interconnected biostable struts and the distal region of the expandable tubular framework is devoid of the bioabsorbable tubular structure; and

wherein the expandable tubular framework has a first outer diameter in the proximal region and a second diameter in the distal region, the first diameter being less than the second diameter.

2. The endoprosthesis of claim 1, wherein the bioabsorbable tubular structure has an outer diameter approximately equal to the second diameter.

3. An endoprosthesis comprising:

an expandable tubular framework having a proximal end, a distal end, and a lumen extending therethrough, the expandable tubular framework including a plurality of interconnected biostable struts;

the expandable tubular framework having a proximal region extending distally from the proximal end to an intermediate location and a distal region extending proximally from the distal end to the intermediate location;

wherein the distal region of the expandable tubular framework is more flexible than the proximal region;

wherein the proximal region of the expandable tubular framework includes a bioabsorbable material disposed on the interconnected biostable struts and the distal region of the expandable tubular framework is devoid of a bioabsorbable material; and

wherein the proximal region of the expandable tubular framework includes a bioabsorbable material disposed in a groove formed in the interconnected biostable struts and the distal region of the expandable tubular framework is devoid of the bioabsorbable material.

4. An endoprosthesis comprising:

an expandable tubular framework having a proximal end, a distal end, and a lumen extending therethrough, the expandable tubular framework including a plurality of interconnected biostable struts;

the expandable tubular framework having a proximal region extending distally from the proximal end to an intermediate location and a distal region extending proximally from the distal end to the intermediate location;

wherein the distal region of the expandable tubular framework is more flexible than the proximal region;

wherein the proximal region of the expandable tubular framework includes a bioabsorbable material disposed on the interconnected biostable struts and the distal region of the expandable tubular framework is devoid of a bioabsorbable material; and

wherein the interconnected biostable struts have a first thickness in the proximal region and the interconnected biostable struts have a second thickness in the distal region, wherein the first thickness is greater than the second thickness.

5. The endoprosthesis of claim 4, wherein the proximal region of the expandable tubular framework includes a bioabsorbable material disposed on the interconnected biostable struts.

6. An endoprosthesis comprising:

an expandable tubular framework having a proximal end, a distal end, and a lumen extending therethrough, the expandable tubular framework including a plurality of interconnected biostable struts;

the expandable tubular framework having a proximal region extending distally from the proximal end to an intermediate location and a distal region extending proximally from the distal end to the intermediate location;

wherein the distal region of the expandable tubular framework is more flexible than the proximal region;

wherein the proximal region of the expandable tubular framework includes a bioabsorbable material disposed on the interconnected biostable struts and the distal region of the expandable tubular framework is devoid of a bioabsorbable material; and

wherein the interconnected biostable struts have a first width in the proximal region and the interconnected biostable struts have a second width in the distal region, wherein the first width is greater than the second width.

7. The endoprosthesis of claim 6, wherein the proximal region of the expandable tubular framework includes a bioabsorbable material disposed on the interconnected biostable struts.

8. An endoprosthesis comprising:

an expandable tubular framework having a proximal end, a distal end, and a lumen extending therethrough, the expandable tubular framework including a plurality of interconnected biostable struts;

the expandable tubular framework having a proximal region extending distally from the proximal end to an intermediate location and a distal region extending proximally from the distal end to the intermediate location;

wherein the distal region of the expandable tubular framework is more flexible than the proximal region;

wherein the proximal region of the expandable tubular framework includes a bioabsorbable material disposed on the interconnected biostable struts and the distal region of the expandable tubular framework is devoid of a bioabsorbable material; and

wherein the interconnected biostable struts have a continuously changing thickness from the proximal region to the distal region, wherein a thickness of the interconnected biostable struts at the proximal end of the expandable tubular framework is greater than a thickness of the interconnected biostable struts at a distal end of the expandable tubular framework.

9. An endoprosthesis comprising:

an expandable tubular framework having a first end, a second end, and a lumen extending therethrough, the expandable tubular framework including a plurality of interconnected bioabsorbable struts;

at least one biostable wire extending generally longitudinally along the expandable tubular framework;

wherein at least one biostable wire is configured to provide longitudinal support to a vessel wall after the expandable tubular framework is absorbed.

10. The endoprosthesis of claim **9**, wherein the at least one biostable wire includes a plurality of biostable wires circumferentially arranged around a circumference of the expandable tubular framework.

11. The endoprosthesis of claim **10**, further comprising a biostable ring attached to the plurality of biostable wires.

12. The endoprosthesis of claim **10**, wherein a first end of the plurality of biostable wires is attached to a first biostable ring and a second end of the plurality of biostable wires is attached to a second biostable ring.

13. A method of implanting an endoprosthesis in a coronary artery proximate an aortic ostium, the method comprising:

positioning the endoprosthesis in the coronary artery with a proximal end of the endoprosthesis proximate the aortic ostium, the endoprosthesis including an expandable tubular framework and having a lumen extending therethrough from the proximal end to a distal end, the expandable tubular framework including a plurality of interconnected biostable struts and a bioabsorbable material disposed on at least a portion of the interconnected biostable struts; and

expanding the expandable tubular framework to exert a radially outward force against the coronary artery;

wherein a proximal region of the endoprosthesis proximate the proximal end has an initial stiffness when expanded greater than an initial stiffness of a distal region of the endoprosthesis; and

wherein the proximal region is configured to have a reduced stiffness less than the initial stiffness over a period of time as the bioabsorbable material is absorbed.

14. The method of claim **13**, wherein the stiffness of the proximal region is reduced at a greater rate than the stiffness of the distal region over the period of time.

15. The method of claim **13**, wherein the proximal region of the expandable tubular framework includes the bioabsorbable material and the distal region of the expandable tubular framework is devoid of a bioabsorbable material, wherein the bioabsorbable material is absorbed over a period of time to reduce the difference in stiffness of the proximal portion relative to the stiffness of the distal portion.

16. The method of claim **13**, wherein the bioabsorbable material is disposed in a groove formed in the interconnected biostable struts in the proximal region.

17. The method of claim **13**, wherein the interconnected biostable struts have a continuously changing thickness from the proximal region to the distal region, wherein a thickness of the interconnected biostable struts at the proximal end of the expandable tubular framework is greater than a thickness of the interconnected biostable struts at a distal end of the expandable tubular framework.

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